

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-166

MICROBIOLOGY REVIEW

REVIEW FOR HFD-580

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 1 of NDA 21-166**

March 17, 2000

- A. 1. APPLICATION NUMBER:** NDA 21-166
- APPLICANT:** Unimed Pharmaceuticals, Inc.
2150 E. Lake Cook Road
Suite 210
Buffalo Grove, IL 60089
(tel) 847-541-2525
- 2. PRODUCT NAME:** Estrogel®
- 3. DOSAGE FORM:** 17 β -estradiol (0.06%) topical gel packaged in a plastic metered-dose pump.
- 4. METHOD OF STERILIZATION:** None (non-sterile product).
- 5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:**
Indicated for the treatment of moderate to severe vasomotor symptoms in menopausal women.
- B. 1. DATE OF INITIAL SUBMISSION:** August 13, 1999
- 2. DATE OF CONSULT:** November 10, 1999
- 3. DATE OF AMENDMENT:** January 6, 2000
- 4. ASSIGNED FOR REVIEW:** November 10, 1999
- 5. RELATED DOCUMENTS:** DMF _____
- C. REMARKS:** A Letter of Authorization by Laboratories Besins Iscovesco, authorizing the Agency to reference DMF _____, was provided in Attachment 4.5.1 of the 1/6/00 amendment. See Microbiologist's Review (dated 3/17/00) of DMF _____ for a review of preservative effectiveness validation.

D. CONCLUSIONS:

The application is recommended for approval for issues concerning microbiological product quality (microbial limits and preservative effectiveness testing). Specific comments are provided in section "E. REVIEW NOTES".

APPEARS THIS WAY
ON ORIGINAL

Neal Sweeney, Ph.D.

cc:

Original NDA 21-166
HFD-580/Division File
HFD-580/D. Spell-LeSane/R. Agarwal
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, March 17, 2000
R/D initialed by P. Cooney, March 17, 2000

5 page(s) have been
removed because it
contains
trade secret
and/or
confidential information
that is not disclosable